


Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>			
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version: 7

<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>		
1.1.	Product identifier	
	Trading name:	HEMATOXYLIN HP, PAP 1B
	Chemical name:	-
	Catalogue number:	HEMHP1B-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Modified hematoxylin acc. to Harris for more intensive nuclear staining acc. to Papanicolaou.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Fax no.:	+385 1 2404039
	e-mail of competent person:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

<b>SECTION 2. Hazards identification</b>		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Eye Irr. 2	H319
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	
	Product identification:	HEMATOXYLIN HP, PAP 1B
	Identification number:	-
	Authorization no.:	-

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

Hazard pictograms:	
	GHS07
Signal word:	Warning
Hazard statements:	H319 Causes serious eye irritation.
Precautionary statements:	P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
Supplemental hazard information (EU):	-
2.3.	Other hazards
	<p><b>Endocrine Disrupting Properties:</b> No known endocrine disrupting properties</p> <p><b>Results of PBT and vPvB assessment:</b> According to the results of its assessment, this substance is not a PBT or a vPvB.</p>

**SECTION 3. Composition/information on ingredients**

CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
7784-31-8/ 616-524-3/ -	-	7 – 8 %	aluminum sulfate octadecahydrate	Eye Dam. 1; H318
107-21-1/ 203-473-3/ 603-027-00-1	01-2119456816- 28-xxxx	10 – 20 %	ethylene glycol	Acute Tox. 4; H302

**SECTION 4. First aid measures**

4.1.	Description of first aid measures	
	General notes:	Take off contaminated clothing.
	Following inhalation:	Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.
	Following skin contact:	Rinse skin with water/shower. In all cases of doubt, or when symptoms persist, seek medical advice.

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

	Following eye contact:	In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.
	Following ingestion:	Rinse mouth. Call a doctor if you feel unwell.
	Self-protection of the first aider:	Treat symptomatically.
<b>4.2.</b>	<b>Most important symptoms and effects, both acute and delayed</b>	
	Following inhalation:	No information available
	Following skin contact:	No information available
	Following eye contact:	Risk of blindness, Risk of serious damage to eyes.
	Following ingestion:	No information available
<b>4.3.</b>	<b>Indication of any immediate medical attention and special treatment needed</b>	
	-	

**SECTION 5. Firefighting measures**

<b>5.1.</b>	<b>Extinguishing media</b>	
	Suitable extinguishing media:	Small fire - water spray, dry powder, foam, CO <sub>2</sub> Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	water jet
<b>5.2.</b>	<b>Special hazards arising from the substance or mixture</b>	
	Hazardous combustion products:	No information available
<b>5.3.</b>	<b>Advice for firefighters</b>	
	Do not enter fire area without proper protective equipment, including respiratory protection.	
<b>5.4.</b>	<b>Additional information</b>	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

**SECTION 6. Accidental release measures**

<b>6.1.</b>	<b>Personal precautions, protective equipment and emergency procedures</b>	
<b>6.1.1.</b>	<b>For non-emergency personnel</b>	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
<b>6.1.2.</b>	<b>For emergency responders:</b>	
	Do not enter fire area without proper protective equipment, including respiratory protection.	

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>			
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version: 7

6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Covering of drains. Take up mechanically.
6.3.2.	Cleaning up:	Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. On land, sweep or shovel into suitable containers. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Place in appropriate containers for disposal.
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

<b>SECTION 7. Handling and storage</b>		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated place.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>			
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version: 7

Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3. Specific end use(s)	
Recommendations:	-
Industrial sector specific solutions:	-

### SECTION 8. Exposure controls/personal protection

8.1. Control parameters				
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m <sup>3</sup>	
Ethylene glycol	107-21-1	20/40	52/104	No information available
Substance name: Aluminium sulphate octadecahydrate				
EC No:	233-135-0	CAS No:	7784-31-8	
<b>DNEL</b>				
<b>Industrial</b>				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	35 mg/ kg (ethylene glycol)	13.4 mg/m <sup>3</sup> (aluminium sulphate octadecahydrate)
Dermal	-	-	-	3.8 mg/kg bw/day (aluminium sulphate octadecahydrate) 106 mg/kg (ethylene glycol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
<b>Consumer</b>				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	7 mg/kg (ethylene glycol)	-

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>			
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version: 7

Dermal	-	-	-	53 mg/kg (ethylene glycol)
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<b>PNEC</b>	
Environmental protection target	PNEC
Fresh water	10 mg/l (ethylene glycol)
Freshwater sediments	37 mg/kg (ethylene glycol)
Marine water	1 mg/l (ethylene glycol)
Marine sediments	3.7 mg/kg (ethylene glycol)
Food chain	No information available
Microorganisms in sewage treatment	199.5 mg/l (ethylene glycol)
Soil (agricultural)	1.53 mg/kg (ethylene glycol)
Air	No information available

8.2.	Exposure controls	
8.2.1.	Engineering measures	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	Chemical protection gloves are suitable, which are tested according to EN 374.  Glove material: nitrile rubber Glove thickness: > 0.11 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	In case of inadequate ventilation wear respiratory protection.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

Substance/mixture related measures to prevent exposure:	See Section 6
Structural measures to prevent exposure:	Use modern equipment.
Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace. Keep away from drains, surface and ground water.
Technical measures to prevent exposure:	See Section 6

**SECTION 9. Physical and chemical properties**

9.1. Information on basic physical and chemical properties			
		Value	Method
Physical state:	liquid		No information available
Color:	red-purple		No information available
Odour/odour threshold:	no odor/no information available		No information available
Melting point / freezing point:	No information available		No information available
Boiling point or initial boiling point and boiling range:	No information available		No information available
Flammability:	No information available		No information available
Lower and upper explosion limit:	No information available		No information available
Flash point:	No information available		No information available
Auto-ignition temperature:	No information available		No information available
Decomposition temperature:	No information available		No information available
pH:	No information available		No information available
Kinematic viscosity:	No information available		No information available
Solubility:	No information available		No information available
Partition coefficient n-octanol/water (log value):	No information available		No information available
Vapour pressure:	No information available		No information available
Density and/or relative density	No information available		No information available
Relative vapour density:	No information available		No information available
Particle characteristics:	No information available		No information available
9.2. Other information			
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**SECTION 10.: Stability and reactivity**

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	No information available.
10.5.	Incompatible materials:	No information available.
10.6.	Hazardous decomposition products:	No information available.

<b>SECTION 11. Toxicological information</b>					
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results
Oral exposure:	anhydrous (ECHA)	rabbit	LD <sub>50</sub>	-	>2.000-<5.000 mg/kg (aluminium sulphate octadecahydrate) 7.712 mg/kg (ethylene glycol)
Dermal exposure:	anhydrous (ECHA)	rat	LD <sub>50</sub>	-	>5.000mg/kg (aluminium sulphate octadecahydrate) >3.500mg/kg (ethylene glycol)
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-	-
	Specific target organ toxicity – single exposure (STOT SE):				
		Specific effects	Target organ	Note	
Oral exposure:		No information available	No information available	-	
Dermal exposure:		No information available	No information available	-	
Inhalation exposure:		No information available	No information available	-	
	Respiratory irritation: No information available				
	Irritation and corrosion				



Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

	Exposure time	Species	Evaluation	Method	Note	
Skin irritation:	-	-	-	-		
Eye irritation:	24 h	rabbit	-	-	Slight irritation	
<b>Sensitization</b>						
Dermal exposure:	No information available					
Inhalation exposure:	No information available					
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>						
Oral exposure:	No information available					
Dermal exposure:	No information available					
Inhalation exposure:	No information available					
Eye exposure:	Causes serious eye damage					
<b>Repeated dose toxicity (subacute, subchronic, chronic)</b>						
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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Specific target organ toxicity – repeated exposure (STOT RE):						
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	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

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CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)						
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Carcinogenicity:	No information available					
Mutagenicity <i>in-vitro</i> :	No information available					
Genotoxicity:	No information available					
Mutagenicity <i>in-vivo</i> :	No information available					
Germ cell mutagenicity:	No information available					
Reproductive toxicity:	No information available					

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Summary of evaluation of the CMR properties:	-					
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11.2.	Information on other hazards:					
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11.2.1.	Endocrine disrupting properties:					
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	No known endocrine disrupting properties that affect human health.					
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11.2.2.	Other informations:					
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<b>SECTION 12. Ecological information</b>
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Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

**12.1. Toxicity**

Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	Fish	ECHA	>85.9 mg/l (aluminium sulphate octadecahydrate) 72.860 mg/l (ethylene glycol)	-
Crustacea:	EC <sub>50</sub>	48 hours	aquatic invertebrates	ECHA	>200 mg/l (aluminium sulphate octadecahydrate) >100 mg/l (ethylene glycol)	-
Algae/aquatic plants	IC <sub>50</sub>	8 days	algae	No information available	6.500-13.000 mg/l (ethylene glycol)	-
Microorganisms	LC <sub>50</sub>	72 hours	-	-	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	EC <sub>50</sub>	180 min	microorganisms	ECHA	>1.000 mg/l (aluminium sulphate octadecahydrate)	-

**12.2. Persistence and degradability**

Abiotic degradation						
	Degradation half-lives		Method		Evaluation	Note
Marine water	No information available		No information available		No information available	-
Fresh water	No information available		No information available		No information available	-
Air	No information available		No information available		No information available	-
Soil	No information available		No information available		No information available	-

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

Biodegradation				
% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

**12.3. Bioaccumulative potential**

Partition coefficient: n-octanol/water (log Kow):						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC <sub>50</sub>	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea ( <i>Daphnia</i> )	EC <sub>50</sub>	No information available	No information available	No information available	No information available	-

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

<b>12.4. Mobility in soil</b>						
Known or predicted distribution in environmental compartments:						
No information available						
Surface tension:						
	Value	°C	Concentration	Method	Note	
	No information available	No information available	No information available	No information available	-	
Adsorption / desorption						
Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-water	No information available	information available	No information available	No information available	No information available	-
Water-air	No information available	information available	No information available	No information available	No information available	-
Soil-air	No information available	information available	No information available	No information available	No information available	-
<b>12.5. Results of PBT and vPvB assessment</b>						
No information available						
<b>12.6. Endocrine disrupting properties</b>						
No known endocrine disrupting properties that affect the environment.						
<b>12.7. Other adverse effects</b>						
No adverse effects are expected.						
<b>SECTION 13. Disposal considerations</b>						
<b>13.1. Waste treatment methods</b>						
<b>13.1.1. Product/Packaging disposal:</b>						
Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.						

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>			
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version: 7

13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-

**SECTION 14. Transport information**

Transporting/shipment by road (ADR)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information: The product is not subject to classification.	

<b>SECTION 15. Regulatory information</b>	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -

Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>				
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version:	7

Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)
National legislation:	<p>Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act</p>
15.2.	Chemical safety assessment
	None

<b>SECTION 16. Other information</b>	
16.1.	<p>Indication of changes: -</p>
16.2.	<p>Abbreviations and acronyms:</p> <p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>



Trading name:	<b>HEMATOXYLIN HP, PAP 1B</b>			
Product code:	HEMHP1B-OT-X**	Revision date:	03 April 2023	Version: 7

16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H: 302 318 319	Harmful if swallowed. Causes serious eye damage. Causes serious eye irritation.
16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

<b>ANNEX: Exposure scenario resulting to Chemical safety assessment</b>	
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